



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/526,065

04/08/2005

Takaaki Terahara

7388/84280

6606

20529

7590

07/31/2008

NATH & ASSOCIATES
112 South West Street
Alexandria, VA 22314

EXAMINER

ELLIS, SUEZU Y

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

07/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,065	Applicant(s) TERAHARA ET AL.	
	Examiner Suezu Ellis	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (EP 1 201 232) in view of Hirano et al. (US 2002/0102290).

With respect to claims 1 and 5-9, Chono et al. discloses a patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with an adhesive agent and pergolide and/or a pharmaceutically acceptable salt thereof [0014], [0015], wherein the adhesive layer comprises an acrylic polymer being a copolymer that includes 2-ethylhexyl acrylate and vinyl acetate [0030], therefore is considered to be having self-adhesion properties as well as being substantially free of carboxyl and hydroxyl groups, and a rubber polymer (SIS) [0030], [0031]. Chono et al. also discloses the acrylic polymer being 10-98% by weight and the rubber polymer being 10-60% by weight [0031]. Chono et al. fails to expressly disclose the weight content ratio of the acrylic polymer to the rubber polymer being only from 1:1 to 1:9. However, with the ranges described above, the weight ratio content of the acrylic polymer to the rubber polymer can be fall between 1:1 and 1:9. Further, Hirano et al.

Art Unit: 1615

demonstrates in Example 1, a pressure-sensitive adhesive comprising an acrylate polymer (2-ethylhexyl acrylate-vinyl acetate copolymer) and a rubber polymer (polyisobutylene and styrene/isoprene/styrene block copolymer), wherein the weight ratio of acrylic polymer to rubber polymer is 1:2. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to create an adhesive layer having good permeability of the drug [0031]. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 4, the modified Chono et al. discloses the adhesive layer comprising an alicyclic saturated hydrocarbon resin-based tackifier [0032]. The modified Chono et al. discloses the tackifier being from 10-70% by weight of the total composition of the adhesive layer, therefore demonstrating the ability to attain a weight ratio of the total content of acrylic polymer and rubber polymer to the content of the tackifier being from 1:1 to 1:9. It would have been obvious to one of ordinary skill in the art to modify the amount of tackifier in order to provide the desired amount of adhesion with the consideration of irritation to the skin at a peeling time [0032]. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 10 and 11, the modified Chono et al. discloses the adhesive agent comprises an organic acid (acetic acid) [0017].

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Hirano et al. and further in view of Terahara et al. (CA 2428181).

With respect to claims 2 and 3, the modified Chono et al. addresses all the limitations of claim 1, however fails to expressly disclose the inclusion of a basic nitrogen-including polymer that includes a basic nitrogen and having no self-adhesion property, wherein the weight ratio of the total content of the acrylic polymer and the rubber polymer to the content of the basic nitrogen-including polymer is from 9:1 to 1:1. Terahara et al. discloses a patch having a basic nitrogen-including polymer being a methyl methacrylate – butyl methacrylate – dimethylaminoethyl methacrylate terpolymer, or polyvinyl acetal diethylamino acetate. (pg. 6, lines 24-25). Terahara et al. further illustrates in Example 5, a formulation having pergolide mesilate that includes an acrylate polymer, a rubber (SIS) and a basic nitrogen-including polymer, wherein the weight ratio of the total content of the acrylic polymer and the rubber polymer to the content of the basic nitrogen-including polymer is from 9:1 to 1:1. It would have been obvious to one of ordinary skill in the art to include a basic nitrogen-including polymer and modify the amount thereof, in order to enhance the skin permeability of the drug, as taught by Terahara et al. (pg. 4, line 21 – pg. 5, line 9).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

Art Unit: 1615

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8 and 12 of copending Application No. 10/469,612 (amendment filed on 10/4/07) in view of Hirano et al.

This is a provisional obviousness-type double patenting rejection.

With respect to claim 1 of the current application, claims 1, 8 and 12 of Application No. 10/469,612 (amended claims filed 10/4/07) discloses:

(claim 1) **A patch comprising a support (functionally equivalent to a backing layer), and an adhesive layer** laid on the support and containing an adhesive base **(adhesive agent)** and a drug, wherein said adhesive base contains an **acrylic polymer substantially having no carboxyl group and no hydroxyl group in molecules thereof**, wherein said polymer is at least one selected from the group consisting of: a 2-ethylhexyl acrylate N-vinyl-2-pyrrolidone 1,6-hexane glycol dimethacrylate copolymer;

Art Unit: 1615

an aminoalkylmethacrylate copolymer E; and a 2-ethylhexyl acrylate vinyl copolymer;
and a rubber-based polymer.

(claim 8) wherein **said drug is at least one selected from** the group consisting of **pergolide, pharmacologically acceptable salts of pergolide**, oxybutynin, and pharmacologically acceptable salts of oxybutynin.

(claim 12) wherein **said drug is selected from the group consisting of pergolide and pharmaceutically acceptable salts of pergolide.**

Claims 1, 8 and 12 of Application No. 10/469,612 fail to expressly disclose the weight ratio of content of the acrylic polymer to content of the rubber polymer being from 1:1 to 1:9. Hirano et al. demonstrates in Example 1, a pressure-sensitive adhesive comprising an acrylate polymer (2-ethylhexyl acrylate-vinyl acetate copolymer) and a rubber polymer (polyisobutylene and styrene/isoprene/styrene block copolymer), wherein the weight ratio of acrylic polymer to rubber polymer is 1:2. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to create an adhesive layer having good permeability of the drug. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments, filed April 23, 2008, with respect to the rejection of claims 1-11 over Terahara et al. have been fully considered and are persuasive. The rejection of claims 1-11 over Terahara et al. has been withdrawn.

Applicant's arguments filed April 23, 2008, with respect to the rejection of claims 1 and 4-11 over Chono et al. in view of Hirano et al., and regarding claims 2 and 3, further in view of Terahara et al., have been fully considered but they are not persuasive.

With respect to the rejection of claims 1 and 4-11 over Chono et al. in view of Hirano et al., argues that Chono et al. nor Hirano et al. does not disclose the combination of components of "pergolide and/or a pharmaceutically acceptable salt thereof, an acrylic polymer substantially free of both hydroxyl and carboxyl groups in the molecule and having self-adhesion properties and a rubber polymer, and a weight ratio of the content of the acrylic polymer to the content of the rubber polymer is from 1:1 to 1:9". Applicant further argues Chono et al. does not teach or suggest the use of pergolide in combination with the polymers. Examiner respectfully disagrees. While Chono et al. does not provide an example having all the claimed elements, examiner notes that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments, and patents are relevant as prior art for all they contain (see MPEP 2123). Further, examiner directs applicant to paragraphs [0030] and [0031]. Para. [0030] recites the same polymers as applicant's claims 1 and 5-8, and para. [0031] recites the combination of the rubber and

Art Unit: 1615

acrylic polymers, and provide for ranges that overlap applicant's claimed ranges. Para. [0030] suggests the use of styrene-isoprene-styrene block copolymer as the rubber polymer, and a copolymer of 2-ethylhexyl acrylate and vinyl acetate as the acrylic polymer, respectively. Therefore, the polymers are considered to have the same properties as that of the instant application (being substantially free of carboxyl and hydroxyl groups). Further, Chono et al. teaches the use of pergolide mesilate in the patch in para. [0015]. Hirano et al. is used as a teaching for demonstrating using a particular ratio of acrylic polymer to rubber polymer in a patch, as desired. Therefore, the rejection of claims 1 and 4-11 over Chono et al. in view of Hirano et al. is maintained.

With respect to claims 2 and 3, applicant argues the individual references of Chono et al., Hirano et al., and Terahara et al. and argues none of the references teaches the combination of components of “pergolide and/or a pharmaceutically acceptable salt thereof, an acrylic polymer substantially free of both hydroxyl and carboxyl groups in the molecule and having self-adhesion properties and a rubber polymer, and a weight ratio of the content of the acrylic polymer to the content of the rubber polymer is from 1:1 to 1:9”. Examiner respectfully disagrees (see above response to arguments). Examiner would like to clarify that Terahara et al. is used as a teaching for the inclusion of the basic nitrogen-including polymer (methyl methacrylate - butyl methacrylate - dimethylaminoethyl methacrylate terpolymer (pg. 6, lines 22-25). Terahara et al. teaches the inclusion of this polymer in order to enhance the skin

Art Unit: 1615

permeability of the drug (pg. 4, lines 19 – pg. 5, line 9). Therefore, one of ordinary skill in the art would appreciate the inclusion of the basic nitrogen-including polymer for the purpose of enhancing the skin permeability of the drug.

Therefore, the rejection of claims 2 and 3 over Chono et al. in view of Hirano et al. and further in view of Terahara et al. is maintained.

With respect to claims 1-11, applicant argues unexpected results of the claimed matrix and directs the examiner to the Tables presented in the instant specification. Examiner respectfully disagrees. Examiner directs applicant to paragraphs [0030] and [0031] of Chono et al. Para. [0030] recites the same polymers as applicant's claims 1 and 5-8, and para. [0031] recites the combination of the rubber and acrylic polymers, and provide for ranges that overlap applicant's claimed ranges. Therefore, one of ordinary skill in the art would expect to try various ratios in order to find the range(s) that provide optimal skin permeability of the drug. Further, the examiner notes that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Terahara et al. teaches the inclusion of the basic nitrogen-including polymer (methyl methacrylate - butyl methacrylate - dimethylaminoethyl methacrylate terpolymer (pg. 6, lines 22-25). Terahara et al. teaches the inclusion of this polymer in order to enhance the skin permeability of the drug (pg. 4, lines 19 – pg. 5, line 9). Therefore, one of ordinary skill in the art would appreciate the inclusion of the basic nitrogen-including polymer for the purpose optimizing the skin permeability of the

Art Unit: 1615

drug as well. Further, while the tables demonstrate a difference in the skin permeability rate, this appears to be a mere difference in degree. In addition, the showings in the examples are not commensurate in scope with the claims. Claim 1 recites "the adhesive layer comprises an acrylic polymer substantially free of both carboxyl group and hydroxyl group and a rubber". The showings provide only one acrylic polymer and one rubber. In order for the showings to be commensurate in scope with the claim, the showings need to demonstrate various types of acrylic polymer and rubbers, not just one type of each. Further, the showing demonstrates the inclusion of additional ingredients, which are not in the claim. The showings would need to demonstrate the adhesive with the rubber and the acrylic polymers alone, without the additional ingredients to demonstrate the additional ingredients have no bearing on the skin permeability results. Thus, applicant's arguments are not persuasive.

Therefore, the rejection of claims 1-11 is maintained.

Examiner notes applicant's request to hold the double patenting rejection in abeyance until the Examiner indicates there is successful resolution of the claim rejections. However, examiner notes that a request to hold a rejection in abeyance is non-responsive. See 37 C.F.R. 1.111. Therefore the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1615

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615